

File date: 08 April 2004

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

4

Complete if Known

Application Number

To be assigned

Filing Date

April 8, 2004

First Named Inventor

Khan et. al.

Group Art Unit

To be assigned

Examiner Name

To be assigned

Attorney Docket Number

3077-6420US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
KRS		#US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,388,668	01-18-1995	Herron	
KRS ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓		#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		#US- 5,851,997	12-22-1998	Harris	
		#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		#US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		#US- 5,968,513	10-19-1999	Gallo et al.	
		#US- 5,997,871	12-07-1999	Gallo et al.	
		#US- 6,319,504	11-20-2001	Gallo et al.	
		#US- 6,319,504 B1	11-20-2001	Gallo et al.	
		#US- 2002/0041871	04-11-2002	Brudnak	
		#US- 2002/0061501	05-30-2002	Khan et al.	
KRS		#US- 6,489,296	12-03-2002	Grinnell et al.	
KRS		#US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		#US- 2003/0113735 A1	06-19-2003	Khan et al.	
KRS		#US- 6,583,109 B1	06-24-2003	Gallo et al.	
		#US- 2003/0113920 A1	06-26-2003	Khan et al.	
KRS		#US- 6,596,688 B1	07-22-2003	Gallo et al.	
KRS		#US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2003/006244 A1	10-02-2003	Murgus et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
KRS ↓ ↓ ↓ ↓ ↓ ↓ ↓		#WO 99/59617	11-25-1999	Erasmus Universiteit		
		#WO 97/49721	12-31-1997	University of Maryland		
		#WO 01/10907 A2	02-15-2001	University of Maryland		
		#WO 01/11048 A2	02-15-2001	University of Maryland		
		#WO 01/72831	10-04-2001	Erasmus Universiteit		
		#2 706 772	12-30-1994	Vacsyn		
		#EP 1 138 892 A1	10/04/2001	Erasmus Universiteit Rotterdam		

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
KRS ↓		US- 5,966,712	10-12-1999	Sabatini et al.	
		US- 6,278,794	08-21-2001	Parekh et al.	
		US- 6,379,970	04-30-2002	Liebler et al.	
		US- 6,507,788	01-14-2003	Camara y Ferrer et al.	
		US- 6,539,102	03-25-2003	Anderson et al.	
		US- 6,711,563	03-23-2004	Koskas	
				April 8, 2004	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
KRS ↓		#EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		#WO 98/35691	08-20-1998	Proscript, Inc.		
		#WO 02/085117	10-31-2002	Elsai Co., Ltd.		
		#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		#DE 19953339	05-17-2001	Goldham Pharma GmbH		
		#96/04008	02-15-1996	Government of the United States		
		#97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49432	12-31-1997	University of Maryland Biotechnology Institute		
		WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	To be assigned
		Filing Date	April 8, 2004
		First Named Inventor	Khan et. al.
		Group Art Unit	To be assigned
		Examiner Name	To be assigned
		Attorney Docket Number	3077-6420US
Sheet	3	of	4

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		#CONNELLY et al., Biphasic Regulation of NF- κ B Activity Underlies the Pro- and Anti-Inflammatory Actions of Nitric Oxide, The Journal of Immunology, 2001, pp. 3873-81, 166, The American Association of Immunologists, USA.	
		#FRIEDLANDER, Tackling anthrax, Nature, November 8, 2001, pp. 160-61, Vol. 414.	
		#MEDZHITOV, Toll-like Receptors and Innate Immunity, Nature Reviews/Immunology, November 2001, pp. 135-45, Vol. 1.	
		#LANG et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", AIDS 1997, Vol. 11, No. 11, pp. 1333-1340.	
		#ISKANDAR et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", Nature Medicine, April 1998, Vol. 4, No. 4, pp. 428-434.	
		#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intensive Care Med, 1998, pp. 1131-38, Vol. 24.	
		#JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.	
		#KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.	
		#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
V		#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, J. Interferon Cytokine Res., 1999, pp. 911-21, Vol. 19.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4

of

4

Complete if Known

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells <i>in Vitro</i> ," 20(5-6) PLACENTA, page A37 (July 1999).	
		#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
		#KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).	
		#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
		#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).	
		#WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).	
✓		#YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).	

Examiner Signature	/Karlheinz Skowronek/	Date Considered	01/05/2007
--------------------	-----------------------	-----------------	------------

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/753,510

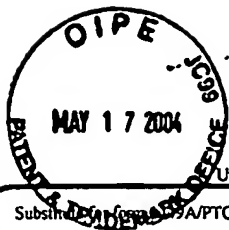
Filed: January 7, 2004

For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Information/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

1

Complete if Known

Application Number	10/821,240
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6384US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
KRS		#US-5,380,668	01-10-1995	Herron	
		#US- 2003/0186244 A1	10-02-2003	Margus et al.	
		#US- 2003/0113733 A1	06-19-2003	Khan et al.	
		#US- 2003/0119720 A1	06-26-2003	Khan et al.	
		#US- 2002/0064501 A1	05-30-2002	Khan et al.	
		#US- 2003/0166556 A1	09-04-2003	Khan et al.	
		#US- 2003/0215434 A1	11-20-2003	Khan et al.	
		#US- 2003/0219425 A1	11-27-2003	Khan et al.	
		#US- 2003/0220257 A1	11-27-2003	Benner et al.	
		#US- 2003/0220258 A1	11-27-2003	Benner et al.	
		#US- 2003/0220259 A1	11-27-2003	Benner et al.	
		#US- 2003/0220260 A1	11-27-2003	Khan et al.	
		#US- 2003/0220261 A1	11-27-2003	Khan et al.	
		#US- 2003/0224995 A1	12-04-2003	Khan et al.	
		#US- 2004/0013661 A1	01-22-2004	Wensvoort et al.	
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
KRS		#WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

Examiner
Signature

/Karlheinz Skowronek/

Date
Considered

01/05/2007

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/753,510

Filed: 1/7/2004

For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

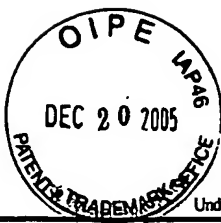
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Copied from 108211140 on 07/27/2004

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



PTO/SB/08B(10-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/821,240
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	1648
Examiner Name	To be assigned
Attorney Docket Number	3077-63841US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		KACHRA et al., "Low Molecular Weight Components but Not Dimeric HCG Inhibit Growth and Down-Regulate AP-1 Transcription Factor in Kaposi's Sarcoma Cells," Endocrinology, 1997, pp. 4038-4041, vol. 138, no. 9.	

Examiner Signature	/Karlheinz Skowronek/	Date Considered	01/05/2007
-----------------------	-----------------------	--------------------	------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



PTO/SB/08B(10-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/821,240
		Filing Date	April 8, 2004
		First Named Inventor	Khan et al.
		Group Art Unit	1648
		Examiner Name	To be assigned
		Attorney Docket Number	3077-63841US
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		IVANOV et al., "Hemoglobin as a Source of Endogenous Bioactive Peptides: The Concept of Tissue-Specific Peptide Pool," Biopolymers, 1997, pp. 171-188, Vol. 39.	
		KHAVINSON et al, Gerontological Aspects of Genome Peptide Regulation, 2005, S. Karger AG, Basel, Switzerland.	
		KHAVINSON et al., "Effects of Livagen Peptide on Chromatin Activation in Lymphocytes from Old People," Bulletin of Experimental Biology and Medicine, October 2002, pp. 389-392, Vol. 134, No. 4.	
		KHAVINSON et al., "Effects of Short Peptides on Lymphocyte Chromatin in Senile Subjects," Bulletin of Experimental Biology and Medicine, January 2004, pp. 78-81, Vol. 137, No. 1.	
		KHAVINSON et al., "Epithalon Peptide Induces Telomerase Activity and Telomere Elongation in Human Somatic Cells," Bulletin of Experimental Biology and Medicine, June 2003, pp. 590-592, Vol. 135, No. 6.	
		KHAVINSON et al., "Inductive Activity of Retinal Peptides," Bulletin of Experimental Biology and Medicine, November 2002, pp. 482-484, Vol. 134, No. 5.	
		KHAVINSON et al., "Mechanisms Underlying Geroprotective Effects of Peptides," Bulletin of Experimental Biology and Medicine, January 2002, pp. 1-5, Vol. 133, No. 1.	
		KHAVINSON et al., "Peptide Promotes Overcoming of the Division Limit in Human Somatic Cell," Bulletin of Experimental Biology and Medicine, May 2004, pp. 503-506, Vol. 137, No. 5.	
↓		MOROZOV et al., "Natural and Synthetic Thymic Peptides as Therapeutics for Immune Dysfunction," Int. J. Immunopharmac., 1997, pp. 501-505, Vol. 19, No. 9/10.	

Examiner Signature	/Karlheinz Skowronek/	Date Considered	01/05/2007
-----------------------	-----------------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

4

Complete if Known

Application Number	10/821,240
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	1631
Examiner Name	R. Negin
Attorney Docket Number	3077-6384US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
KRS		#US- 4,427,660	01-1984	Schiffman et al.	
		#US- 4,571,336	02-1986	Houck et al.	
		#US- 4,753,965	06-1988	Stemerick et al.	
		#US- 4,855,285	08-1989	Stevens	
		#US- 5,002,961	03-1991	Dage et al.	
		#US- 5,854,004	12-1998	Czemilofsky et al.	
		#US- 5,223,397	06-1993	Pouletty	
		#US- 5,801,193	09-1998	Ojo-Amaize et al.	
		#US- 5,942,494	08-1999	Ginsberg et al.	
		#US- 5,972,924	10-1999	Keep et al.	
		#US- 5,994,126	11-1999	Steinman et al.	
		#US- 5,981,486	11-1999	Matsushima et al.	
		#US- 6,051,596	04-2000	Badger	
		#US- 6,075,150	06-2000	Wang et al.	
		#US- 6,150,500	11-2000	Salerno	
		#US- 6,235,281	05-2001	Stenzel et al.	
		#US- 6,310,041	10-2001	Haddox et al.	
		#US- 6,361,992	03-2002	Szkudlinski et al.	
		#US- 2003/0148955	08-2003	Pluenneke	
		#US- 6,630,138	10-2003	Gerlitz et al.	
		#US- 6,831,057	12-2004	Baldwin et al.	
		#US- 6,844,315	01-2005	Khan et al.	
		#US- 2004/0208885 A1	10-21-2004	Khan et al.	
		US- 2005/0214943 A1	09-29-2005	Khan et al.	
		US- 2005/0227925 A1	10-13-2005	Benner et al.	
		US- 2006/0111292 A1	05-25-2006	Khan et al.	
		US- 2006/0142205 A1	06-29-2006	Benner et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
KRS		#WO 98/34631 A1	08-1998	Thomas Jefferson University		
KRS		#WO 2001/83554 A2	11-2001	Praecis Pharmaceuticals Incorporated et al.		
KRS		GB 2 194 886 A	03-23-1988	The Wellcome Foundation Limited		
Examiner Signature		Date Considered				

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known

Application Number	10/821,240
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	1631
Examiner Name	R. Negin
Attorney Docket Number	3077-6384US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		#ABRAHAM, E., "Coagulation Abnormalities in Acute Lung Injury and Sepsis," Am. J. Respir. Cell Mol. Biol., 2000, pp. 401-404, Vol. 22.	
		#ADIB-CONQUY et al., "NF-kappaB Expression in Mononuclear Cells in Patients with Sepsis Resembles That Observed in Lipopolysaccharide Tolerance," Am. J. Respir. Crit. Care Med., 2000, pp. 1877-1883, Vol. 162.	
		#ARIMA et al., "IL-2-Induced Growth of CD8+ T Cell Prolymphocytic Leukemia Cells Mediated by NF-kappaB Induction and IL-2 Receptor alpha Expression," Leukemia Research, 1998, pp. 265-273, Vol. 22, No. 3.	
		#BAEUERLE et al., "Function and Activation of NF-kappaB in the Immune System," Annu. Rev. Immunol., 1994, pp. 141-179, Vol. 12.	
		#BETHEA et al., "Traumatic Spinal Cord Injury Induces Nuclear Factor-kappaB Activation," The Journal of Neuroscience, 1 May 1998, pp. 3251-3260, Vol. 18, No. 9.	
		#BODFISH et al., "Treating the Core Features of Autism: Are We There Yet?" Mental Retardation and Developmental Disabilities Research Reviews, 2004, pp. 318-326, Vol. 10.	
		#BROWN et al., "Two Forms of NF-kappaB1 (p105/p50) in Murine Macrophages: Differential Regulation by Lipopolysaccharide, Interleukin-2, and Interferon-gamma," Journal of Interferon and Cytokine Research, 1997, pp. 295-306, Vol. 17.	
		#CUI et al., Am. J. Physiol. Integr. Comp. Physiol., 2004, pp. R699-R709, Vol. 286.	
		#DWINNELL et al., Atlas of Diseases of the Kidney, Blackwell Sciences, 1999, pp. 12.1-12.12, Ch. 12.	
		#EMMEL et al., "Cyclosporin A Specifically Inhibits Function of Nuclear Proteins Involved in T Cell Activation," Science, 22 December 1989, pp. 1617-1620, Vol. 246.	
		#EPINAT et al., "Diverse agents act at multiple levels to inhibit the Rel/NF-kappaB signal transduction pathway," Oncogene, 1999, pp. 6896-6909, Vol. 18.	
		#FAUST et al., "Disseminated intravascular coagulation and purpura fulminans secondary to infection," Bailliere's Clinical Haematology, 2000, 179-197, Vol. 13, No. 2.	
		#JIMENEZ-GARZA et al., "Early Effects of Modulating Nuclear factor-kappaB Activation on Traumatic Spinal Cord Injury in Rats," Ann. N.Y. Acad. Sci., 2005, pp. 148-150, Vol. 1053.	
		#KALNS et al., Biochem. Biophys. Res. Comm., 2002, pp. 41-44, Vol. 292.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 4

Complete if Known

Application Number	10/821,240
Filing Date	April 8, 2004
First Named Inventor	Khan et al.
Group Art Unit	1631
Examiner Name	R. Negin
Attorney Docket Number	3077-6384US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		#KALNS et al., Biochem. Biophys. Res. Comm., 2002, pp. 506-09, Vol. 297.	
		#KIDD et al., "Autism, An Extreme Challenge to Integrative Medicine. Part II: Medical Management," Alternative Medicine Review, 2002, pp. 472-499, Vol. 7, No. 6.	
		#KRONFOL et al., "Cytokines and the Brain: Implications for Clinical Psychiatry," Am. J. Psychiatry, May 2000, pp. 683-694, Vol. 157, No. 5.	
		#LI et al., "NF-kappaB Regulation in the Immune System," Nature Reviews/Immunology, October 2002, pp. 725-734, Vol. 2.	
		#MALEK-AHMADI, P., "Role of Cytokines in Psychopathology: Therapeutic Implications," Drug News Prospects, June 1998, pp. 271-276, Vol. 11, No. 5.	
		#MCBEAN et al., "Rodent Models of Global Cerebral Ischemia: A Comparison of Two-Vessel Occlusion and Four-Vessel Occlusion," Gen. Pharmac., 1998, pp. 431-434, Vol. 30, No. 4.	
		#MCDONALD et al., "Interleukin-15 (IL-15) Induces NF-kappaB Activation and IL-8 Production in Human Neutrophils," Blood, 15 December 1998, pp. 4828-4835, Vol. 92, No. 12.	
		#Merck Index, 17th ed. 1999, pp. 1145-1146, 1841-1848, 2539, 2551.	
		#Merriam-Webster Medical Dictionary, 1994, p. 82.	
		#MOAYERI et al., Journal of Clinical Investigation, September 2003, pp. 670-82, Vol. 112, No. 5.	
		#NEELY et al., "Then and now: Studies using a burned mouse model reflect trends in burn research over the past 25 years," Burns, 1999, pp. 603-609, Vol. 25.	
		#NGO et al., The protein folding problem and tertiary structure prediction, 1994, pp. 492-94.	
		#PELLIZZARI et al., FEBS Letters, 1999, pp. 199-204, Vol. 462.	
		#SAMANIEGO et al., Induction of Programmed Cell Death in Kaposi's Sarcoma Cells by Preparations of Human Chorionic Gonadotropin, Journal of the National Cancer Institute, January 20, 1999, pp. 135-43, Vol. 91, No. 2.	
		#SMITH et al., "Recent developments in drug therapy for multiple sclerosis," Multiple Sclerosis, 1999, pp. 110-120, Vol. 5.	
		#TRAYSTMAN, R., "Animal Models of Focal and Global Cerebral Ischemia," ILAR Journal, 2003, pp. 85-95, Vol. 44, No. 2.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/821,240
		Filing Date	April 8, 2004
		First Named Inventor	Khan et al.
		Group Art Unit	1631
		Examiner Name	R. Negin
		Attorney Docket Number	3077-6384US
Sheet	4	of	4

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
KRS		#WEINBERGER et al., "Mechanisms Mediating the Biologic Activity of Synthetic Proline, Glycine, and Hydroxyproline Polypeptides in Human Neutrophils," Mediators of Inflammation, 2005, pp. 31-38, Vol. 1.	
KRS		#YANG et al., "Increased cortical nuclear factor kappaB (NF-kappaB) DNA binding activity after traumatic brain injury in rats," Neuroscience Letters, 1995, pp. 101-104, Vol. 197.	

Examiner Signature	/Karlheinz Skowronek/	Date Considered	01/05/2007
-----------------------	-----------------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/028,075

Filed: December 21, 2001

For: GENE REGULATOR, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.